

Food and Drug News . . .

Important Information for California Consumers and Food Processors

*California Department of Health Services
Food and Drug Branch*

*October 7, 2004
Issue Number F-1-2004*

Food Labels

The goal of food labeling is to provide consumers with information that is factual and relevant.

The food label allows consumers to compare one product to another, gives instructions for safe handling and storage, lists ingredients to help consumers select foods with ingredients they want or need to avoid, and identifies the firm responsible for the product.

Certain label information, such as the responsible firm's name and address and ingredient declaration, is required. Other label information such as health claims and terms that describe a food's nutrient content is voluntary. Additional mandatory label information was added as the result of three federal laws that became effective: the Nutrition Labeling and Education Act of 1990 (NLEA), the American Technology Preeminence Act of 1991 (ATPA), and Dietary Supplement Health and Education Act of 1994 (DSHEA). The U.S. Food and Drug Administration (FDA) published a number of regulations implementing these three laws. California adopts all the federal labeling regulations, and has its own laws with additional labeling requirements. Regulations implemented under NLEA:

■ require nutrition information on almost all processed foods,

■ provide a new format for presenting nutrition information (i.e., "Nutrition Facts" panel),

■ set definitions for nutrient content claims such as "low-fat",

■ provide appropriate use of fifteen scientifically proven health claims, and

■ require ingredient listing on all foods with two or more ingredients.

Under ATPA, food firms have to list the net contents of their products in both metric units and English (inch-pound) units. These changes are intended to make food label information more accurate and useful to consumers.

Label Panels

A food package usually has at least two distinct areas: the principal display panel (PDP), and the information panel (IP). The PDP is the part of the label consumers see first when selecting a food product. Therefore, in most cases, the PDP is the front of the package. The IP is usually to the immediate right of the PDP (to the left, rear, top or bottom if there is insufficient space to the right of the PDP). The PDP is where information such as the name of the product and the net quantity of contents is located, while the IP is mainly reserved for nutrition information, the ingredient list, and the name and

address of the responsible firm (manufacturer, packer or distributor). All required information on the label must be legible. It cannot be concealed in any manner such that it is unlikely to be read by the consumer. The size of the lettering, unless stated, must be at least 1/16 inch (there are exceptions for small, single-serving packages. Refer to 21 CFR §101.2 for details). All required information must be in English. Accurately translated information in another language may accompany it.

Labels must be made of materials that do not contaminate the food product. If there is likelihood that the paper, ink or adhesive of a label will touch the product or penetrate the packaging, these materials must be safe for food use.

Food Name

All foods must be named. This name, which is often called the "statement of identity," is either the "common name" of the food or a "fanciful name." If a fanciful name is used, it must be accompanied by a descriptive phrase at least 1/2 the type size of the product name. The name has to be truthful. If it is a "flavored" product, it must so state (e.g., "cherry flavored" pie). If the flavor is not derived from a natural source, then it must so indicate (e.g., "artificial cherry flavored"

pie). When appropriate, it must describe the form of the food too, such as "sliced peaches" or "whole peaches". A brand name can serve as the statement of identity if the name is commonly used and understood by consumers to refer to a specific food (e.g., Pepsi Cola, Coca-Cola).

Responsible Firm

There must be a firm identified on the label as a responsible party. The firm's name, city, state and zip code must be declared. If the firm is not in the current telephone directory for that city, the street address must also be listed. Beginning January 1, 2002, all labels of bottled water must bear bottler's or brand name owner's telephone number and address.

Net Quantity

Every packaged food must declare its count, net weight (drained weight if appropriate) or volume. The net quantity refers only to the quantity of food in a package or container. It includes the weight of any liquid in which the food may be packed if the liquid is usually eaten. It does not include the weight of the container or wrappers. It must be stated in both English (inch-pound) units and metric units. For example, Net Wt 8 oz (226 g).

Ingredients

All packaged foods composed of two or more ingredients (including standardized foods) are required to include an ingredient list. Foods with two or more discrete components (e.g., cherry pie that has filling and piecrust) may have a separate ingredient list for each of the components. For foods that are sold from bulk, a list of ingredients

must be stated on a sign or on the food's original container. The ingredient declaration must be legible and be correctly listed in descending order of predominance by weight. Ingredients must be listed by their "common names." Certain ingredients require special declaration (for more information about the special declaration, see 21 CFR §101.4).

Product Dates

Certain foods [e.g., infant formula, dairy products, and potentially hazardous foods (PHF) that are in oxygen-reduced atmosphere or in containers that creates anaerobic conditions] are required to have an expiration date, while product dating is optional for other foods. There are two types of dating on food packaging: "open dating" and "code dating". In open dating, dates are stated alphabetically, such as "July 10", or numerically such as "7-10" or "710." In code dating, the information is coded in letters, numbers and symbols that only the firm (manufacturer) can translate. (See "Refrigerated Foods" below for the definition for PHF).

Open dating includes "pull date," "quality assurance or freshness date", "pack date" and "expiration date." Manufacturers have the pull date, quality assurance date or pack date on labels to inform retailers and consumers when the product was made or how long their products will be of optimum quality. Expiration date is the date before which a product should be eaten. Open dating is recommended for all foods that are readily perishable.

Code dating enables the manu-

facturer to convey a relatively large amount of information (such as production code and date, location of production and/or packaging) with a few small letters, numbers and symbols. In the case of recall, it makes it easier to quickly identify and track down the product and remove it from the marketplace.

Nutrition Labeling

Most processed and packaged foods (except exempt foods) must declare information about the foods' nutritional content using formats under the heading "Nutrition Facts" (see attached sample nutrition facts format). Variations in the format and criteria for the variations are defined in the regulations (21 CFR §101.9). For instance, certain foods may qualify for a simplified format. This format is allowed when the food contains insignificant amounts of seven or more of the mandatory nutrients.

The following foods, provided that they neither bear nutrition information nor make nutrient content claims or health claims on their labels, are exempt from the mandatory NLEA nutrition labeling requirements: food produced by small businesses (the exemption applies to businesses with fewer than 100 full-time equivalent employees and fewer than 100,000 units of the product sold in the previous year; Please refer to www.cfsan.fda.gov/~dms/sbel.html for details); restaurant food; ready-to-eat food prepared primarily on site; food sold by food service vendors and vending machines; food shipped in bulk as long as it is not for sale in that form to consumers; medical food

and infant formula; and food containing no significant amount of any nutrients.

Nutrient Content Claims

Eleven basic terms have been defined for several nutrients, and FDA has set conditions for the use of these terms. The terms are: free, low, reduced, fewer, high, less, more, lean, extra lean, good source, and light. For example, the term "sodium free" means that the food contains less than 5 milligrams of sodium per serving of the food.

(For details, please refer to 21 CFR 101.13 and 101.25 to 101.69)

Health Claims

NLEA allows manufacturers to make certain claims linking the effect of a nutrient or food to a disease or health-related condition. FDA has approved the following fifteen claims and defined conditions under which the claims can be used. The approved claims are:

- a diet high in calcium and a lower risk of osteoporosis (21CFR 101.72),
- a diet low in total fat and reduced risk of some cancer (21CFR 101.73),
- a diet low in saturated fat and cholesterol and reduced risk of coronary heart disease (21CFR 101.75),
- a diet rich in fiber-containing grain products, fruits and vegetables and reduced risk of some cancers (21CFR 101.76),
- a diet rich in fruits, vegetables and grain products that contain fiber and reduced risk of coronary heart disease (21CFR 101.77),
- a diet low in sodium and reduced risk of high blood

pressure (21CFR 101.74),

- a diet rich in fruits and vegetables and a reduced risk of some cancers (21CFR 101.78).
- a diet rich in folate and reduced risk of neural tube defects (21CFR 101.79).
- a diet low in sugars and starches and less likelihood of tooth decay (21CFR 101.80).
- a diet rich in soluble fiber from certain foods and reduced risk of coronary heart disease (21CFR 101.81).
- soy protein and reduced risk of coronary heart disease (21CFR 101.82).
- plant sterol/stanol and reduced risk of coronary heart disease (21CFR 101.83).
- conventional foods that contain eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) omega-3 fatty acid and reduced risk of coronary heart disease.
- whole grain foods and risk of heart disease and certain cancer (claim authorized based on authoritative statements by federal scientific bodies).
- potassium and the risk of high blood pressure and stroke (claim authorized based on authoritative statements by federal scientific bodies).

(For details, please visit <http://vm.cfsan.fda.gov/~dms/flg-6c.html>)

Structure or Function Claims

A conventional food label may bear statements about a substance's effect on the structure or function of the body provided that such statements do not claim to diagnose, mitigate, treat, cure, or prevent disease and are not false or misleading. Additionally, the claimed effect must be achieved

through nutritive value. (For detail, visit

<http://www.cfsan.fda.gov/~dms/ds-ltr15.html> and <http://www.cfsan.fda.gov/~dms/hcl-aims.html>).

Juice Products

The federal regulations (21CFR 120.1-120.25) require that, beginning January 20, 2004, all manufacturers must produce juice products under a Hazard Analysis and Critical Control Point (HACCP) plan, that must include a method to consistently achieve a 5-log reduction of the most resistant microorganism of public health significance that are likely to occur in the juice. Juice is defined as the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree. For beverages containing less than 100 percent juice, only the juice ingredient must comply with HACCP requirement. All beverages containing juice must declare the percent of total juice on the information panel. If the label of a multi-juice beverage names one or more juices and the named juices are present in minor amounts, it may either state the beverage is flavored by the named juice, such as "raspberry flavored juice drink," or declare the amount of the named juice in a 5 percent range, as "juice blend, 2 to 7 percent raspberry juice." Juice produced and sold at retail is exempt from the HACCP plan requirement and 5-log reduction, however raw juice must be prominently and conspicuously labeled with the warning

statement: **“WARNING:** This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.”

Refrigerated Foods

The California Health and Safety Code (H&SC) requires that all potentially hazardous foods (PHF) have the statement "Perishable Keep Refrigerated" on the label in a conspicuous location. PHF is defined as a food, which is capable of supporting growth of infectious or toxicogenic microorganisms when held at temperatures above 45 degrees Fahrenheit. In general, PHF does not include foods that have a pH level of 4.6 or below, a water activity value of 0.85 or less, or food products in hermetically sealed containers processed to prevent spoilage.

The statement "Perishable Keep Frozen" is also acceptable on the label of foods that are frozen.

Confectionery Products Containing Alcohol

If a confectionery product contains alcohol in excess of ½ of 1 percent by weight, the fact must be stated on the label of the food. If a facility sells directly to consumers such confectionery products that are unpackaged or unlabeled, the facility owner must provide a written notice to consumers of that fact (H&SC 110695, 113985). Confectionery products must not contain any alcohol in excess of 5 percent by weight (H&SC 110590).

Organic Foods

Foods represented as “organic”

must meet the requirements of the USDA National Organic Program (NOP) Regulations and the California Organic Products Act of 2003. Products may be labeled as “100% organic” or “organic” if they are comprised of 100% certified organic ingredients or 95% certified organic ingredients, respectively (minus water and salt).

Product containing between 70% and 95% certified organic ingredients may make a “Made with Organic” claim on their label. Organic products must be certified by a third party accredited certifying organization, and that organization’s name must appear on the information panel of the organic food product. For additional organic labeling information, you can visit the NOP website at www.ams.usda.gov/nop or you can contact any of the Food and Drug Branch (FDB) Offices.

Safe Handling Instructions

Raw meat and poultry products (fresh and frozen) including shell eggs must bear safe handling instructions on their labels. The handling instructions should address safe storage of raw product, prevention of cross-contamination, cooking of raw product, and/or handling of leftovers. For example, shell egg cartons are required to bear a statement “To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly” (65FR 76091, 12/5/00). Further, the California Uniform Retail Food Facility Law (H&SC 113997) additionally requires that retail egg containers be prominently labeled “Refrigerate after purchase” or that a conspicuous sign be posted advising consumers that these eggs

must be refrigerated as soon as practical after purchase. For detailed information on meat and poultry products, consumers can call the U.S. Department of Agriculture, Food Safety and Inspection Service (USDA-FSIS) Meat and Poultry Hot Line.

Other Label Declarations

There are many optional statements that can be made on a label. These include: storage and thawing information, directions for use, product pictures or vignettes, Universal Product Code (UPC), trade marks and copyrights, and religious symbols.

Dietary Supplements

Dietary supplements are under different regulations from those for processed foods. The regulations implementing DSHEA (62FR 49826, 09/23/97; 65FR 999, 01/06/00) and those in Title 17, California Code of Regulations (17 CCR):

- define a dietary supplement as a product, intended to supplement the diet, which contains one or more dietary ingredients such as vitamins, minerals, herbs or botanicals, and amino acids. They are intended for ingestion in such forms as capsules, powders, softgels, gelcaps, tablets or liquids. They must not be represented as a sole item of a meal or diet.

- requires that the label include the following information: 1) statement of identity that identifies the product as a dietary supplement, 2) net quantity of contents, 3) if a structure-function claim is made, the label must bear the statement “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat,

cure, or prevent disease,” 4) directions for use, 5) “Supplement Facts” panel, 6) other ingredients not listed in the Supplement Facts panel in descending order of predominance and by common name or proprietary blend, and 7) name and address of the manufacturer, packer or distributor.

- set parameters for use of the terms “high potency” and “antioxidant,” and for making the “structure or function” claims,
- for botanical ingredients, identify on the label the part of the plant used to make the product.
- require products containing substances that have stimulant laxative effects to bear the following statement on their labels: “NOTICE: This product contains [name of substance(s) that can have stimulant laxative effects and common name(s) if different]. Read and follow directions carefully. **Do not use if you have or develop diarrhea, loose stools, or abdominal pain.** Consult your physician if you have frequent diarrhea, or if you are pregnant, nursing, taking medication, or have a medical condition.” The 17 CCR Sections 10200 et seq. describe this requirement in detail and provide a list of substances that have stimulant laxative effects.

Food Label Questions

If you have questions about labeling laws and regulations or feel that a label is misleading, please contact any of the FDB Offices.

FDB does not approve labels. It is the responsibility of the firm identified on the label to ensure that the information on its label is accurate, truthful, and in compliance with pertinent laws and regulations. For designing, format-

ting and proofing labels, a competent “food label consultant” should be retained. A list of food label consultants in your area may be obtained by contacting trade organizations for food or the Institute of Food Technologists (IFT; phone number 312-782-8424). For questions regarding the labeling of foods containing more than 3 percent meat or poultry products, processors should contact the USDA-FSIS Meat and Poultry Hot Line or its Western Region. Information on labeling of foods to be imported or exported can be obtained from the FDA. The California Department of Food and Agriculture’s Milk and Dairy Foods Safety Branch can provide labeling information for milk and dairy products.

FDB Offices

South: 1449 West Temple Street, Room 224, Los Angeles, CA 90026
(213) 580-5719

North: 1500 Capitol Ave., P.O. Box 997413, MS-7602 Sacramento, CA 95899-7413
(916) 650-6500

Other Agencies

FDA, San Francisco District Office, Compliance Branch
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
(510) 337-6700

FDA, Los Angeles District Office, Compliance Branch
19701 Fairchild
Irvine, CA 92612
(949) 608-2900

USDA-FSIS, Meat and Poultry Hot Line, 1-800-535-4555 or
(202) 720-3333.

USDA-FSIS
620 Central Ave., Bldg. 2-C
Alameda, CA 94501
(510) 337-5000

California Department of Food and Agriculture, Milk and Dairy Food Safety Branch,
1220 N Street,
Sacramento, CA 95814
(916) 654-0773

References

California Sherman Food, Drug, and Cosmetic Law §110425-111223 and §113700-114475 (CURFFL)

Title 17, California Code of Regulations §10200 to 10750

Title 21, Code of Federal Regulations (21 CFR), Part 100-109, April 1, 2004 (4/1/2004)

56 Federal Register (FR), 60880-60891, 11/27/1991;
58 FR 2066-2941, 1/6/1993;
58 FR 17085-17173, 4/1/1993;
58 FR 17328-17346, 4/2/1993;
58 FR 44020-44090, 8/18/1993;
58 FR 60105-60109, 11/15/1993;
59 FR 350-426, 01/04/1994;
59 FR 24039, 5/10/1994;
59 FR 24232-24250, 05/10/1994;
62 FR 49826-49892, 09/23/97;
63 FR 37029-37056, 07/08/98;
65 FR 999-1050, 01/06/00;
65 FR 76091-76114, 12/05/00;
66 FR 6137-6202, 01/19/01;

A Food Labeling Guide, FDA;
<http://vm.cfsan.fda.gov/~dms/flg-2.html>;
<http://vm.cfsan.fda.gov/~dms/flg-4.html>;
<http://vm.cfsan.fda.gov/~dms/flg-6c.html>;
<http://www.cfsan.fda.gov/~dms/nutrguid.html>;
<http://www.cfsan.fda.gov/~lrd/hhssupp2.html>;
<http://www.fda.gov/bbs/topics/news/2004/NEW01115.html>

<http://www.cfsan.fda.gov/~dms/flg-6c.html>;
<http://www.fda.gov/ola/2003/dietarysupplements1028.html>;

How To Read The New Food Label, FDA and American Heart Association, FDA 93-2260

Sample Nutrition Facts Panel:

Nutrition information must be set off in a box 101.9(d)(1)(i)

Number of servings per container 101.9(b)(8) & (d)(3)(ii)

Bold Printed Nutrients 101.9(d)(1)(iv)

101.9(c)(1)

101.9(c)(2)

101.9(c)(3)

101.9(c)(4)

101.9(c)(6)

101.9(c)(7)

Nutrition Facts			
Serving Size ½ cup (114g)			
Servings Per Container 4			
Amount Per Serving			
Calories	260	Calories from Fat	120
		% Daily Value*	
Total Fat	13g		20%
Saturated Fat	5g		25%
Cholesterol	30mg		10%
Sodium	660mg		28%
Total Carbohydrate	31mg		10%
Dietary Fiber	0g		0%
Sugars	5g		
Protein	5g		
Vitamin A 4%		Vitamin C 2%	
Calcium 15%		Iron 4%	
*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:			
		Calories:	2,000 2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g
Calories per gram:			
Fat 9 • Carbohydrate 4 • Protein 4			

Required Heading 101.9(d)(2)

Household measure 101.9(b)(7) & 101.9(d)(3)(i)

Amount per serving 101.9(d)(4)

101.9(c)(1)(ii)

101.9(d)(6)

101.9(d)(7)

101.9(c)(2)(i)

101.9(c)(6)(i)

101.9(c)(6)(ii)

Vit/Min List order 101.9(c)(8)(iv)

101.9(d)(8)

101.9(d)(9)

Calorie conversion optional 101.9(d)(10)

For calculation of %DV

RDI 101.9(c)(8)(iv)

DRV 101.9(c)(9)

Type/Layout

6 & 8 points 101.9(d)(1)(iii)

6 point may be used for:

"Amount Per Serving"

"% Daily Value"

Caloric conversion footnote

Daily Value footnote

Hairline Rule 101.9(d)(1)(v)

SUMMARY OF NUTRITION LABELING RULES FOR DIETARY SUPPLEMENTS:

Dietary supplement containing dietary ingredient
with and without RDI's and DRV's:

Supplement Facts		
Serving Size 1 Packet		
Amount Per Packet		% Daily Value
Vitamin A (from cod liver oil)	5,000 IU	100%
Vitamin C (as ascorbic acid)	250 mg	417%
Vitamin D (as ergocalciferol)	400 IU	100%
Vitamin E (as d-alpha tocopherol)	150 IU	500%
Thiamin (as thiamin mononitrate)	75 mg	5000%
Riboflavin	75 mg	4412%
Niacin (as niacinamide)	75 mg	375%
Choline (as choline chloride)	100 mg	*
Betaine (as betaine hydrochloride)	25 mg	*
Glutamic Acid (as L-glutamic acid)	25 mg	*
Inositol (as inositol monophosphate)	75 mg	*
para-Aminobenzoic acid	30 mg	*
Deoxyribonucleic acid	50 mg	*
Boron	500 mcg	*

* Daily Value not established.
Other ingredients: Cellulose, stearic acid and silica.

Dietary supplement of an herb

Supplement Facts	
Serving Size 1 Capsule	
Amount Per Capsule	
Oriental Ginseng, powdered (root)	250 mcg*

* Daily Value not established.
Other ingredients: Gelatin, water, and glycerin.

A proprietary blend of dietary ingredients:

Supplement Facts		
Serving Size 1 tsp (3 g) (makes 8 fl oz prepared)		
Servings Per Container 24		
	Amount Per Teaspoon	% Daily Value
Calories	10	
Total Carbohydrate	2 g	< 1%*
Sugars	2 g	†
Proprietary blend	0.7 g	
German Chamomile (flower)		†
Hyssop (leaves)		†

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Other ingredients: Fructose, lactose, starch, and stearic acid.

1. Title, "Supplement Facts," will allow for easy identification.
2. Information must be listed "per serving." Serving sizes are determined by manufacturer's recommendations for consumption at one occasion.
3. Nutrients required in nutrition labeling of conventional foods must be listed when present and omitted when not present.
4. "Other dietary ingredients" (e.g., botanicals, phytochemicals) that do not have recommendations for daily consumption are listed beneath a bar. They are required to state the quantity present and to be identified as having no recommendations for consumption.
5. The list of dietary ingredients in the nutrition label (nutrients and non-nutrients) may include the source ingredient. If so, the source need not be listed again in the ingredient list.
6. Botanicals must state the part of the plant present and be identified by their common or usual name. In addition, their Latin binomial name is needed if the common or usual name is not listed in Herbs of Commerce published by the American Herbal Products Association.
7. Proprietary blends may be listed with the weight given for the total blend only. When this is done, components of the blend must be listed in descending order of predominance by weight.

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